

Drug Safety Oversight Board Roster

Chair (Non-voting)

- Douglas Throckmorton, M.D., Deputy Director for Regulatory Programs
Center for Drug Evaluation and Research

Executive Secretary (Non-voting)

- Steven Osborne, M.D.
Executive Director of the Drug Safety Oversight Board
Center for Drug Evaluation and Research

Center for Drug Evaluation and Research

Primary Member:

- Robert Temple, M.D., Deputy Director for Clinical Science
Center for Drug Evaluation and Research

Office of New Drugs, Center for Drug Evaluation and Research

Primary Members:

- Mwango Kashoki, M.D.,M.P.H., Associate Director for Safety, Office of New Drugs
- Mary Parks, M.D., Director, Division of Metabolism and Endocrinology Products

Alternate Members:

- John Jenkins, M.D., Director, Office of New Drugs
- Sandra Kweder, M.D., Deputy Director, Office of New Drugs
- Ellis Unger, M.D., Deputy Director, Office of Drug Evaluation 1
- Andrea Leonard-Segal, Director, Division of Nonprescription Clinical Evaluation

Office of Medical Policy, Center for Drug Evaluation and Research

Primary Member:

- Elizabeth Donohoe, M.D., M.H.S.A., Medical Officer, Immediate Office

Alternate Member:

- Kathleen Uhl, M.D., Deputy Director, Office of Medical Policy
- Denise Hinton, CDR, U.S. Public Health Service, Supervisory Senior Program Management Officer

Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research

Primary Members:

- Mark I. Avigan, M.D., Director, Division of Drug Risk Evaluation
- Judy Staffa, Ph.D., R.Ph., Acting Associate Director for Regulatory Research

Alternate Members:

- Gerald Dal Pan, M.D., Director, Office of Surveillance and Epidemiology
- Henry « Skip » Francis, M.D., Deputy Director, Office of Surveillance and Epidemiology
- Carol A. Holquist, R. Ph., Director, Division of Medical Errors and Technical Support
- Ann McMahon, M.D., M.S., Deputy Director, Division of Drug Risk Evaluation
- Solomon Iyasu, M.D., M.P.H., Director, Division of Epidemiology

Office of Translational Sciences, Center for Drug Evaluation and Research

Immediate Office

Primary Member:

- Marc Walton, M.D., Ph.D., Associate Director, Office of Translational Sciences

Alternate Member:

- ShaAvhree Buckman, M.D., Ph.D., F.A.A.P. Acting Director, Office of Translational Sciences

Office of Biostatistics

Primary Member:

- Robert O'Neill, Ph.D., Director, Office of Biostatistics

Alternate Member:

- Aloka Chakravarty, Ph.D., Director, Division of Biometrics

Office of Clinical Pharmacology

Primary Member:

- Darrell Abernethy, M.D., Ph.D., Associate Director of Drug Safety, Office of Clinical Pharmacology

Alternate Member:

- Lawrence Lesko, Ph.D., Director, Office of Clinical Pharmacology

Office of Communications

Primary Member:

- Julie Zawisza, Director, Office of Communications

Alternate Member:

- Kimberly Rawlings, Acting Deputy Director, Office of Communications
- Gregory Busse, Ph.D., Writer / Editor, Office of Communications

Office of Compliance, (CDER)

Primary Member:

- Ilisa B.G. Bernstein, Pharm. D., J.D., Acting Deputy Director, Office of Compliance

Alternate Member:

- Charles E. Lee, M.D.CAPT, USPHS, Div. of New Drugs and Labeling Compliance, Office of Compliance

Office of the Center for Drug Evaluation and Research

Safe Use Initiative Team

Primary Member:

- Karen Weiss, M.D. M.P.H., Associate Director for Medical Affairs, Office of the Center Director

Alternate Member:

- Dale C. Slavin, Ph.D., Safe Use Initiative, Policy Analyst, Office of the Center Director

Office of Pharmaceutical Science, Center for Drug Evaluation and Research

Primary Member:

- Laurie Muldowney, M.D. Medical Officer

Alternate Member:

- Nancy Chang, M.D., Office of Generic Drugs

Center for Biologics Evaluation and Research, Food and Drug Administration

Primary Member:

- Robert Ball, M.D., M.P.H., M.S.S., Director, Office of Biostatistics and Epidemiology

Alternate Member:

- Rickey Wilson, M.D., Director, Division of Epidemiology

Center for Devices and Radiological Health, Food and Drug Administration

Primary Member:

- Robert L. Becker, Jr., M.D., Ph.D., Chief Medical Officer, Office of In Vitro Diagnostic Device Evaluation and Safety

Alternate Member:

- pending

Federal Partners

Agency for Healthcare Research and Quality

Primary Member:

- Anne E. Trontell, M.D., M.P.H., Sr. Advisor on Pharmaceutical Outcomes and Risk Management

Alternate Member:

- Scott R. Smith, Ph.D., Director, Pharmaceutical Outcomes Research, Center for Outcomes and Evidence

Centers for Medicare and Medicaid Services

Primary Member:

- Jeffrey A. Kelman, M.D., MMsc., Chief Medical Officer

Alternate Member:

- Judith A. Geisler, R.Ph., CHC, Director, Division of Formulary and Benefit Operations
- Monica Reed, PharmD., LT, USPHS, Division of Formulary and Benefit Operations

Centers for Disease Control and Prevention

Primary Member:

- Dan Budnitz, M.D., M.P.H., CAPT, USPHS, Director, Medication Safety Program, Division of Healthcare Quality Promotion

Alternate Member:

- Nadine Shehab, PharmD., M.P.H., Division of Healthcare of Quality Promotion

Department of Defense

Primary Member:

- William G. Davies, R.Ph., M.S., Director, DoD Pharmacy Utilization Management/ TRICARE Mgmt. Activity

Alternate Member:

- George E. Jones, Jr., Colonel, USAF, BSC, Deputy Chief, Pharmaceutical Ops Directorate

Department of Defense (Clinical)

Primary Member:

- John Kugler, M.D., Deputy Chief Medical Officer

Alternate Member

- Ron Wyatt, M.D., Chief of Patient Safety Center

Health Resources and Services Administration

Primary Member:

- Karen C. Williams, MBA, PharmD, Senior Program Management Officer, Office of Pharmacy Affairs

Alternate Member:

- Jae Choi, PharmD., LtCDR USPHS, Office of Pharmacy Affairs
- Dorcas Ann Taylor, PharmD., J.D., Policy Analyst, Office of Pharmacy Affairs

Indian Health Service

Primary Member:

- Michael Lee, Pharm.D., NCPS, BCPS, LCDR, USPHS, Chair, IHS NCPS Committee, Vice-Chair (A), IHS National P&T Committee, Assistant Chief Pharmacist, Claremore Indian Hospital

Alternate Member:

- Joseph Bryant, Pharm.D., BCPS, LCDR, U.S. Public Health Service, Supervisor, Pharmacy Support Branch, IHS National Supply Service Center

National Institutes of Health, National Cancer Institute

Primary Member:

- Kevin Conlon, M.D., Senior Investigator, Metabolism Branch

Alternate Member:

- Pamela Jo Harris, M.D., F.A.C.P., Senior Investigator, Investigational Drug Branch, Cancer Therapy Evaluation Program

National Institute of Health, Office of Director

Primary Member:

- Jacqueline Corrigan-Curay, M.D., J.D., Acting Director, Office of Biotechnology Activities

Alternate Member

- Amy P. Patterson, M.D., Director, Office of Science Policy

Department of Veterans Affairs

Primary Member:

- C. Bernie Good, M.D., M.P.H., Chairman, Medical Advisory Panel for Pharmacy Benefits Management, Veterans Administration Pittsburgh Healthcare System

Alternate Member:

- Peter Glassman, MBBS, M.Sc., Staff Physician, Department of Veterans Affairs, VA Greater Los Angeles Healthcare System
- Walid F. Gellad, M.D., M.P.H., Department of Veterans Affairs, Veterans Administration Pittsburgh Healthcare System

Primary Member

- Mark Enderle, M.D. Department of Veterans Affairs, Veterans Administration Arkansas Healthcare System

Alternate Member:

- pending